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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
11/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/752,899	BUNICK ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,8,9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8,9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response dated 9-8-10 is acknowledged.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, 8-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,667,050 B1 to Boissonneault et al ('050) in view of US 3,619,292 to Brouillard ('292) and further in view of Olmo et al OR US 6,667,050 B1 to Boissonneault et al ('050) and US 4,684,534 to Valentine ('534) in view of US 3,619,292 to Brouillard ('292) and Olmo et al.

'050 teach a chewable tablet composition comprising an active ingredient and carriers such as dextrose, microcrystalline cellulose, polyvinylpyrrolidone etc (all of which are claimed in the instant) and sucralose (examples). The examples of '050 contain sucralose as a sweetener. '050 teach the same binders and disintegrants that are also claimed in the instant invention but fail to teach dextrose monohydrate. The compositions of '050 do not necessarily require fat, non-saccharide water soluble binder or aspartame (claims 1, 8 and 11) (examples 3 and 6) and thus meet the claimed limitation. The examples of '050 teach the claimed disintegrants and lubricants (see examples) and other auxiliary ingredients of claim 12 (examples and col. 5-6).

'050 teach dextrose but not dextrose monohydrate and the claimed particle sizes.

'292 teach forming a free-flowing tablet containing a binder or a binder-filler, which is a sugar granule. The sugar granule comprises aggregates of cohered microcrystals of dextrose (abstract and col. 1, L 1- 20). According to '292 dextrose hydrate provides more advantages when employed in direct compression than in wet granulation or dry granulation because it produces a cooling effect when dissolved in the mouth, which is highly desirable for a tableted food or a pharmaceutical and can also enhance the flavor in the tablet (col. 2, L 10-35), particularly chewable drug tablets (col. 5, KL 55-58).

Olmo studied the role of directly compressible excipients based on dextrose, such as Emdex and Maltrin M510, in compressed tablets. The tablets were tested at four different hardness to give a target hardness of 2, 4, 6, 7, 9, 10 and 12 kP (page 774, col. 1). According to Olmo compressed tablets prepared with Emdex (hydrated dextrose) has a faster disintegration time and faster release than Maltrin M10 (abstract and figure 6). Olmo teaches that tablets with high bulk density and low porosity such as with Emdex imparts high flow rate (table 2) to the tablets and the high crushing strength (figure 4). Figure 3 shows the relationship between the compression force and crushing strength of the tablets with Emdex and Maltrin prepared by wet granulation or direct compression, where it is seen that the direct compressed tablets with Emdex provided higher crushing strength. Olmo concludes that the compressed tablets prepared with Emdex resulted in highest mechanical strength and yet faster disintegration compared with Maltrin.

Valentine '534 teaches a chewable tablet composition comprising excipient base materials such as carbohydrate based agglomerate materials including dextrose, dextrose monohydrate, fructose, sucrose etc., which are held together by small quantities of binding materials such as maltodextrin (col. 2-3). The carbohydrate agglomerates are in the size range of 20 to 100 microns (col. 4, L 29-35 & col. 9, lines 20-42) and particulate active agent having a particle size of about 50 microns (col. 4). '534 teaches at least 25% by weight of the carbohydrate agglomerate and in particular, claim 3 recites 90% to 99% by weight for a quick melting tablet. Valentine clearly states that the tablet is prepared by direct compression (col. 1, L 57-63).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the particulate agglomerated carbohydrates or granules such as dextrose monohydrate (of Valentine '534 or '292 or Olmo et al) in the composition of '050 for preparing directly compressed tablets because Valentine '534 teach that dextrose and dextrose monohydrate are equally effective for compressibility, the tablets are highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active agent. Further '292 also teach that dextrose monohydrate particles disintegrate very quickly in the mouth and enhance the flavor of the tablet. Olmo also teaches directly compressible dextrose monohydrate with high strength and faster disintegration.

Claim 14 recites the same limitation i.e., the ratio of dextrose monohydrate to sucralose, which was presented previously in claim 1. With respect to the ratio of dextrose monohydrate and sucralose, the example compositions of '050 contain high

amounts of dextrose compared to the sweeteners such as sucralose and aspartame. In this regard, applicants have not established any unexpected advantage with the claimed ratio and accordingly choosing the appropriate amounts of binders and sweeteners to achieve the desired effect would have been within the scope of a skilled artisan.

Response to Arguments

2. Applicant's arguments filed 9-8-10 have been fully considered but they are not persuasive.

Applicants state that the use of directly compressible dextrose monohydrate imparts a smooth, creamy texture and fast melt-away to soft tablets that are designed for chewing or dissolving in the mouth prior to swallowing. Its inclusion in the tablets of the present invention facilitates the manufacture of tablets without the need to include fats and water soluble binders. It is submitted that dextrose monohydrate is known to have a relatively high water liability as storage temperatures increase. Thus, unbound water may be present which increases the possibility of a reaction between dextrose and excipients within the tablet. It is submitted that surprisingly, the inventors have discovered that the inclusion of sucralose is advantageous, since sucralose is a high intensity sweetener that does not react with dextrose in the presence of increased levels of water (see Declaration of Frank Bunick, dated April 7, 2009).

Applicants argue that Neither Boissonneault et al., Brouillard et al. nor Valentine appreciate the difference between dextrose monohydrate and directly compressible dextrose monohydrate. The distinction between the two enables one to manufacture chewable tables without the use of fats and water soluble binders. It is argued that

Boissonneault et al., Brouillard et al. and/or Valentine do not disclose or suggest the understanding that the use of directly compressible dextrose monohydrate comes with the liability of greater quantities of unbound water present at high storage temperatures due to the presence of hydrated dextrose. It is argued that the unbound water may facilitate a reaction between the dextrose and excipients within the tablet, which may result in browning or discoloration of the tablet; and that this problem was resolved by the present inventors who realized that the use of sucralose as a high intensity sweetener instead of aspartame, prevented the discoloring and/or browning reaction from occurring. Applicants argue that Olmo et al. discloses the use of EMDEX, a hydrated dextrose that was used as an excipient in a directly compressible tablet formulation but like Boissonneault et al., Brouillard et al. and/or Valentine, Olmo et al. also does not recognize the problem created when a hydrated dextrose is used, where there is an increase in unbound water in the tablet at high storage temperatures. Thus, according to applicants Olmo et al. would not recognize that the problem may be avoided by using sucralose as a high intensity sweetener. Therefore, applicants submit that the proposed combinations of Boissonneault et al., Brouillard et al. and Olmo et al. or Valentine, Brouillard et al. and Olmo et al. would not result in a chewable tablet containing a directly compressible dextrose monohydrate and sucralose. It is argued that the cited references show no appreciation or understanding that the use of directly compressible dextrose monohydrate may give rise to the presence of unbound water which increases the possibility of a reaction between dextrose and excipients within the tablet; and that by including sucralose as a high intensity sweetener, the possibility of

browning or discoloration due to a reaction with dextrose in the presence of increased levels of water is removed. It is argued that claim 12 is similar to Claim 1 and also includes a directly compressible dextrose monohydrate. Applicants argue that claims 2, 3, 5, 8, 9, 11 and 14 depend from Claim 1, and Claim 13 depends from Claim 12 and that these claims are also believed to be patentable over the cited references, since they depend from a patentable base claim.

In response to applicant's argument that the prior art does not recognize the advantage of combining sucralose with directly compressible dextrose monohydrate, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Applicanst' arguments are not found persuasive because instant claims are directed to a composition and not a method. The rejection of record addressed the deficiency of 050 B1 to Boissonneault et al., and provided the teachings of Brouillard, Olmo and Valentine for the claimed compressible dextrose monohydrate and the particle sizes. The prior art recognizes the advantages of including compressible dextrose monohydrate in directly compressible tablets, which in addition to other components also contain claimed sucralose, for achieving cooling effect when dissolved in the mouth (Brouillard); and faster disintegration times, high flow rate and high crushing strength (Olmo). Thus, even though the prior art does not suggest the same reasoning as that of applicants for the combination of compressible dextrose monohydrate and sucralose, prior art provides motivation to include compressible

dextrose monohydrate in a chewable tablet that contains sucralose and the argued advantage would naturally flow from the suggested combination. Therefore, a skilled artisan would have expected the prevention or inhibition of any browning or discoloration caused hydrated dextrose monohydrate by the presence of sucralose of 050 B1 to Boissonneault et al., because by applicants' own admission, the unbound water may facilitate a reaction between the dextrose and excipients within the tablet, which may result in browning or discoloration of the tablet; and that this problem was resolved by the present inventors who realized that the use of sucralose as a high intensity sweetener instead of aspartame, prevented the discoloring and/or browning reaction from occurring. Hence, the argued superior results are not unexpected from the teachings of the prior art. Applicants' arguments regarding the declaration and the teachings of the cited references have been addressed in detail in the previous action and are incorporated herewith. Applicants' arguments with respect to claim 12 and dependent claims 2, 3, 5, 8, 9 and 11-14 are not found to be persuasive for the reasons above.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611